UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/887,220	BOSCH ET AL.
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>22 June 2001</u>.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-20</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-20</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>15 November 2001</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date <u>15 January 2003</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1.   This communication is in response to the application filed on 22 June 2001.

Claims 1-20 are pending. The IDS statements filed on 15 January 2003 and 04 October

2001 have been entered and considered.

Claim Rejections - 35 USC § 112

2.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

3.   Claims 1, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as

being incomplete for omitting essential steps, such omission amounting to a gap

between the steps. See MPEP § 2172.01.

(A)   As per Claim 1, 11 and 13, Applicant claims a process for improving operations

of clinics and other medical facilities. It is unclear how statistically analyzing said data

to compute a sigma comprising a standard deviation around a mean of said data to

determine the performance of said process would improve the process.

4.   Claims 1, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

(A)   As per Claims 1, 11 and 13, it is unclear how a sigma is computed from

statistically analyzing said data.

Claim Rejections - 35 USC § 103

5.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

6.   Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Ash (5,536,412; hereinafter Ash), in view of Salvatore Di Filippo ("KT/V Or Solute

Removal Index: Problems In Measuring and Interpreting the Results" 1998. Nephrology

Dialysis Transplantation. pgs. 13: 2199-2202; hereinafter Filippo), further in view of

Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher-Haynes), further in view

of Seare et al. (5,557,514; hereinafter Seare), further in view of Siegrist, Jr. et al.

(5,652,842; hereinafter Siegrist), and further in view of Claudia H. Deutsch ("Managers

Seek Corporate Nirvana Through Quality Control" Dec. 7, 1998. The New York Times.

pg. C.1.; hereinafter Deutsch).

(A)   As per Claim 1, Ash discloses a process for improving operations of clinics and

other medical facilities to enhance care and treatment of patients requiring blood

purification, comprising the steps of:

(a)   treating patients requiring blood purification at least one facility, said

treating comprising providing each patient with an extracorporeal blood

treatment (Rx), said extracorporeal blood treatment comprising removing

blood from the patient, treating the blood externally to the patient by

removing matter from the blood and returning the treated blood to the

patient (Ash: col. 4, lines 31-56; Fig. 1); and

(b)   said extracorporeal blood treatment being selected form the group

consisting of hemodialysis, dialysis, ultrafiltration, hemofiltration,

hemodiafiltration, plasmapherisis, and apherisis (Ash: col. 4, lines 41-63)

(Examiner also notes Applicant's admission (that these treatment

procedures are old and well known in the art), in the background of the

invention of the present application (09/887,220), that states the following:

"Several procedures known for this purpose are dialysis, hemodialysis,

hemofiltration, hemodiafiltration, ultrafiltration; and plasmapherisis."

(hereinafter Admission #1).

Ash, however, fails to expressly disclose a process for improving operations of

clinics and other medical facilities to enhance care and treatment of patients requiring

blood purification, comprising the steps of:

(c)   measuring the effectiveness of each treatment per patient;

(d)   measuring the efficiency of each treatment per patient by determining the

         time for each treatment of each patient;

(e)   determining the frequency of said treatments for each patient;

(f)   determining costs of each of said treatments per patient;

(g)   calculating total costs of said treatments for each patients;

(h)   calculating variations of effectiveness of said treatments for each patient;

(i)   calculating variations of efficiency of said treatments for each patient;

(j)   calculating variations of costs of said treatments for each patient;

(k)   identifying patient characteristics for each patient by measuring the weight

         and height of each patient and determining the sex and age of each

         patient;

(l)   identifying demographics of each facility including the geographical

         location of each facility;

(m)   comparing and correlating data comprising said measured effectiveness

and efficiency of said treatments per patient, said frequency of treatment

per patient, said costs of said treatment per patient, said variations in

effectiveness, efficiency and costs of said treatments per patient, said

patient characteristics, and said demographics of each facility; and

(n)   statistically analyzing said data to compute a sigma comprising a standard

deviation around a mean of said data to determine the performance of

said process.

Nevertheless, these features are old and well known in the art, as evidenced by

Filippo, Fletcher-Haynes, Seare, Siegrist and Deutsch. In particular, these prior art

references disclose a process for improving operations of clinics and other medical

facilities to enhance care and treatment of patients requiring blood purification,

comprising the steps of:

(c)   measuring the effectiveness of each treatment per patient (Filippo: pgs.

2199-2202) (Examiner also notes that use of the Daugirdas formula (i.e.,

KT/V) in the dialysis arts to assess effectiveness/efficiency is well known

and obvious.);

(d)   measuring the efficiency of each treatment per patient by determining the

time for each treatment of each patient (Filippo: pgs. 2199-2202)

(Examiner also notes that use of the Daugirdas formula (i.e., KT/V) in the

dialysis arts to assess effectiveness/efficiency is well known and

obvious.);

(e)   determining the frequency of said treatments for each patient (Fletcher-

Haynes: pg. 20, par. [0167]; Fig. 6A) (Examiner notes that the frequency

of treatments for each patient is evident via Fletcher-Haynes' procedure

log.);

(f)   determining costs of each of said treatments per patient (Seare: abstract;

col. 1, lines 20-33; col. 27, lines 44-58) (Examiner also notes that

determining/calculating/analyzing various operational costs (e.g., cost of

treatment) is a common practice followed by businesses/organizations

(e.g., medical facilities) in order to effectively manage their

business/organization. As such, Examiner considers this feature well

known and obvious.);

(g)   calculating total costs of said treatments for each patients (Seare:

abstract; col. 1, lines 20-33; col. 27, lines 44-58) (Examiner also notes that

determining/calculating/analyzing various operational costs (e.g., total

costs of treatment) is a common practice followed by

businesses/organizations (e.g., medical facility) in order to effectively

manage their business/organization. As such, Examiner considers this

feature well known and obvious.);

(h)   calculating variations of effectiveness of said treatments for each patient

(Filippo: pgs. 2199-2202) (Examiner also notes that

determining/calculating/analyzing effectiveness/efficiency of a business/organization process (e.g., patient treatment) is a common practice followed by businesses/organizations (e.g., medical facility) in order to effectively manage their business/organization. As such, Examiner considers this feature well known and obvious.);

(i)   calculating variations of efficiency of said treatments for each patient (Filippo: pgs. 2199-2202) (Examiner also notes that determining/calculating/analyzing effectiveness/efficiency of a business/organization process (e.g., patient treatment) is a common practice followed by businesses/organizations (e.g., medical facility) in order to effectively manage their business/organization. As such, Examiner considers this feature well known and obvious.);

(j)   calculating variations of costs of said treatments for each patient (Seare: abstract; col. 1, lines 20-33; col. 27, lines 44-58) (Examiner also notes that determining/calculating/analyzing various operational costs (e.g., treatment cost variations) is a common practice followed by businesses/organizations (e.g., medical facilities) in order to effectively manage their business/organization. As such, Examiner considers this feature well known and obvious.);

(k)   identifying patient characteristics for each patient by measuring the weight and height of each patient and determining the sex and age of each patient (Fletcher-Haynes: pg. 3, par. [0020]; Fig. 4B);

(l)   identifying demographics of each facility including the geographical

location of each facility (Siegrist: col. 4, lines 25-40; col. 7, lines 55-67;

Figs. 8C and 12b)

(Examiner notes that identifying demographic information (e.g.,

geographical location) of a facility is standard information that

businesses/organizations document for operations management

purposes. Examiner also notes that Siegrist teaches the entry of various

data (e.g., demographics, etc.) pertaining medical facilities. In particular,

Figure 8c depicts a client hospital graphical user interface field displaying

a hospital ID code, city location (i.e., geographical location), and hospital

name.).

(m)   comparing and correlating data comprising said measured effectiveness

and efficiency of said treatments per patient, said frequency of treatment

per patient, said costs of said treatment per patient, said variations in

effectiveness, efficiency and costs of said treatments per patient, said

patient characteristics, and said demographics of each facility (Seare:

abstract; col. 1, lines 20-33; col. 27, lines 44-58) (Examiner also notes that

comparing and correlating various operational data (e.g., effectiveness of

treatments per patient, etc.) is a common practice followed by

businesses/organizations (e.g., medical facilities) in order to effectively

manage their business/organization. As such, Examiner considers this

feature well known and obvious.); and

(n)   statistically analyzing said data to compute a sigma comprising a standard

deviation around a mean of said data to determine the performance of

said process (Deutsch: pgs. 1-5) (Examiner notes that statistical analysis

of process data is a common practice of businesses/organizations and

that sigma, in particular, is a well-known statistical measure used by

businesses/organizations for managing and improving their processes.).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Filippo with the teachings of Ash with the motivation of

measuring the amount of dialysis (Filippo: pg. 2199).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Fletcher-Haynes with the combined teachings of Ash and

Filippo with the motivation of enhancing process efficiency and business management

(Fletcher-Haynes: pg. 2, par. [0013]).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Seare with the combined teachings of Ash, Filippo and

Fletcher-Haynes with the motivation of providing a mechanism for assessing medical

services utilization patterns (Seare: col. 4, lines 28-32).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Siegrist with the combined teachings of Ash, Filippo, Fletcher-

Haynes and Seare with the motivation of storing information to be used for process

improvement and business management purposes (Siegrist: col. 2, lines 55-64).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Deutsch with the combined teachings of Ash, Filippo, Fletcher-Haynes, Seare and Siegrist with the motivation of providing a way to identify the optimum configuration of a process (Deutsch: pg. 1).

(B)   As per Claim 2, Ash fails to expressly disclose a process as in Claim 1 wherein:

(a)   said facility is a medical treatment facility; and

(b)   said medical treatment facility is a hospital.

Nevertheless, these features are old and well known in the art, as evidenced by Fletcher-Haynes. In particular, Fletcher-Haynes discloses a process as in Claim 1 wherein:

(a)   said facility is a medical treatment facility (Fletcher-Haynes: pg. 24, par. [0195]) (Examiner has noted insofar as Claim 2 recites "selected from the group consisting of a medical treatment facility and a home of a patient," a medical treatment facility has been recited.); and

(b)   said medical treatment facility is a hospital (Fletcher-Haynes: pg. 24, par. [0195]) (Examiner has noted insofar as Claim 2 recites "selected from the group consisting of a clinic, a hospital, a center for medical treatment, a

patient treatment facility of a health care provider, and an office of a

physician," a hospital has been recited.).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Fletcher-Haynes with the combined teachings of Ash, Filippo,

Seare, Siegrist and Deutsch with the motivation of enhancing process efficiency and

business management (Fletcher-Haynes: pg. 2, par. [0013]).

(C)   As per Claim 3, Ash fails to expressly disclose a process as in Claim 1 wherein

the effectiveness of each treatment is measured according to the mathematical model

KT/V wherein K = clearance, T = time of said treatment, and V = body distribution

volume of urea or creatine.

Nevertheless, these features are old and well known in the art, as evidenced by

Filippo. In particular, Filippo discloses a process as in Claim 1 wherein the

effectiveness of each treatment is measured according to the mathematical model KT/V

wherein K = clearance, T = time of said treatment, and V = body distribution volume of

urea or creatine (Filippo: pgs. 2199-2202) (Examiner also notes that use of the

Daugirdas formula (i.e., KT/V) in the dialysis arts to assess effectiveness/efficiency is

well known and obvious.).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Filippo with the teachings of Ash, Fletcher-Haynes, Seare,

Siegrist and Deutsch with the motivation of measuring the amount of dialysis (Filippo: pg. 2199).

(D)   As per Claim 4, Ash fails to expressly disclose a process as in Claim 3 wherein said statistically analyzing further comprises calculating a standard deviation for said effectiveness of said treatment by statistical computation by calculating a standard deviation for intra patient KT/V.

Nevertheless, these features are old and well known in the art, as evidenced by Filippo. In particular, Filippo discloses a process as in Claim 3 wherein said statistically analyzing further comprises calculating a standard deviation for said effectiveness of said treatment by statistical computation by calculating a standard deviation for intra patient KT/V (Filippo: pgs. 2199-2202) (Examiner has noted insofar as Claim 4 recites "selected from the group consisting of: calculating a standard deviation for KT/V for each patient, calculating a standard deviation for inter patient KTN, and calculating a standard deviation for intra patient KT/V," a standard deviation for intra patient KT/V has been recited. Moreover, Examiner notes that standard deviation is a statistical measure of the dispersion or uncertainty in a random variable and because of its mathematical tractability standard deviation is a useful measure of the spread in a set of data and is often employed within the dialysis arts for statistical analysis and inferential statistics. As such, Examiner considers calculating a standard deviation for effectiveness of a patient treatment (e.g., KT/V, KTN, etc.) by statistical computation well known and obvious.).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Filippo with the combined teachings of Ash, Fletcher-Haynes, Seare, Siegrist and Deutsch with the motivation of measuring the amount of dialysis (Filippo: pg. 2199).

(E)   As per Claim 5, Ash fails to expressly disclose a process as in Claim 1 wherein:

    (a)   said calculating are computed electronically by a central processing unit (CPU);

    (b)   said comparing are performed electronically by said CPU;

    (c)   said statistically analyzing are computed electronically by said CPU; and

    (d)   said CPU is a computer.

Nevertheless, these features are old and well known in the art, as evidenced by Siegrist. In particular, Siegrist discloses a process as in Claim 1 wherein:

    (a)   said calculating are computed electronically by a central processing unit (CPU) (Siegrist: pg. 2, lines 66-67; pg. 3, lines 24-31; Fig. 1);

    (b)   said comparing are performed electronically by said CPU (Siegrist: pg. 2, lines 66-67; pg. 3, lines 24-31; Fig. 1);

    (c)   said statistically analyzing are computed electronically by said CPU (Siegrist: pg. 2, lines 66-67; pg. 3, lines 24-31; Fig. 1); and

(d)   said CPU is a computer (Siegrist: pg. 2, lines 66-67; pg. 3, lines 24-31;

Fig. 1) (Examiner has noted insofar as Claim 5 recites "selected from the

group consisting of a: microprocessor, computer, main frame computer,

server computer, desktop computer, workstation computer, notebook

computer, laptop computer, notebook computer, palm pilot-type computer,

computer chip, integrated circuit, electronic controller, network, internet,

and global communications network," a computer has been recited.).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Siegrist with the combined teachings of Ash, Filippo, Fletcher-

Haynes, Seare and Deutsch with the motivation of storing information to be used for

process improvement and business management purposes (Siegrist: col. 2, lines 55-

64).

(F)   As per Claim 7, Ash fails to expressly disclose a process as in Claim 1 wherein:

(a)   said data further comprises supplemental data selected from the group

consisting of facility data, patient data, and cost data;

(b)   said facility data comprising demographic information consisting of

division;

(c)   said patient data comprising patient information determined from each

patient, consisting of race of patients; and

(d)   said cost data comprising financial data consisting of dialyzer costs per

        treatment.

Nevertheless, these features are old and well known in the art, as evidenced by

Siegrist. In particular, Siegrist discloses a process as in Claim 1 wherein:

(a)   said data further comprises supplemental data selected from the group

        consisting of facility data, patient data, and cost data (Siegrist: col. 3, lines

        31-48; col. 4, lines 53-65; Figs. 1-6);

(b)   said facility data comprising demographic information consisting of division

        (Siegrist: col. 9, lines 16-19; Table VII; Examiner considers

        categories/units to read on "division.") (Examiner has noted insofar as

        Claim 7 recites "selected from the group consisting of: metropolitan

        statistical area of each facility defining an urban MSA, ownership of each

        facility, type of ownership of each facility including company owned and

        joint venture facilities, length of service of each facility, hospitalization of

        patients, division, and employee turnover (T/O) at each facility," division

        has been recited.);

(c)   said patient data comprising patient information determined from each

        patient, consisting of race of patients (Siegrist: col. 3, lines 31-48; col. 4,

        lines 53-65; Figs. 1-6) (Examiner has noted insofar as Claim 7 recites

        "selected from the group consisting of: type of treatment per patient,

duration (months) of treatments per patient, percentage of patients having

said treatment as a primary cure for their ailments, race of patients, ethnic

background of each patient, hemoglobin per patient, albumen per patient,

catheter usage per patient, equipment usage per patient, temperature

conditions during treatment, humidity conditions during treatment, type of

equipment and supplies, composition of dialysis fluids, noncompliance per

patient, iron supplement usage per patient, epogen usage per patient,

crude mortality rate (CMR) of patients in said facility,

average months on dialysis (MOD) per patient, modified charleson

comorbidity index (MCCII)," race of patients has been recited.); and

(d)   said cost data comprising financial data consisting of dialyzer costs per

treatment (Siegrist: col. 3, lines 31-48; col. 4, lines 53-65; Figs. 1-6)

(Examiner has noted insofar as Claim 7 recites "selected from the group

consisting of: equipment costs per treatment, dialyzer costs per treatment,

costs of supplies per treatment, costs for sterilizing dialysis equipment for

said treatments, savings and costs for reuse of equipment for said

treatment, labor costs per treatment, overhead per facility, percentage of

patients covered by commercial insurance, reimbursement of medicare for

said treatments, reimbursements from government agencies for said

treatments, and reimbursement from insurance companies for said

treatments," dialyzer costs per treatment has been recited.).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Siegrist with the combined teachings of Ash, Filippo, Fletcher-Haynes, Seare and Deutsch with the motivation of storing information to be used for process improvement and business management purposes (Siegrist: col. 2, lines 55-64).

(G)   As per Claim 8, Ash discloses a process as in Claim 1 including mapping of said process (Ash: col. 2, lines 39-53).

(H)   As per Claim 9, Ash fails to expressly disclose a process as in Claim 1 including operating said process at about one sigma.

Nevertheless, these features are old and well known in the art, as evidenced by Deutsch. In particular, Deutsch discloses a process as in Claim 1 including operating said process at about one sigma (Deutsch: pgs. 1-5).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Deutsch with the combined teachings of Ash, Filippo, Fletcher-Haynes, Seare and Siegrist with the motivation of providing a way to identify the optimum configuration of a process (Deutsch: pg. 1).

7.   Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash, Filippo, Fletcher-Haynes, Seare, Siegrist and Deutsch as applied to claims 1-5 and 7-9 above, and further in view of Perley et al. (US 2002/0103730; hereinafter Perley).

(A)   As per Claim 6, Ash fails to expressly disclose a process as in Claim 5 including:

    (a)   electronically calculating financial results of said process for said

        treatment of said patients at said facilities with said CPU;

    (b)   said financial results are EBITDA;

    (c)   said EBITA comprising earnings before interest, taxes and amortization;

        and

    (d)   said EBITDA comprising earnings before interest, taxes, depreciation and

        amortization.

Nevertheless, these features are old and well known in the art, as evidenced by

Perley. In particular, Perley discloses a process as in Claim 5 including:

    (a)   electronically calculating financial results of said process for said

        treatment of said patients at said facilities with said CPU (Perley: abstract;

        pg. 4, par. [0050]; Fig. 4-5);

    (b)   said financial results are EBITDA (Perley: pg. 4, par. [0050]; Fig. 4-5)

        (Examiner has noted insofar as Claim 6 recites "selected from the group

        consisting of: earnings, operating income, gross income, net income,

        gross margin, net margin, profits, EBITA and EBITDA," EBITDA has been

        recited.);

(c)   said EBITA comprising earnings before interest, taxes and amortization

(Perley: pg. 4, par. [0050]; Fig. 4-5) (Examiner notes that EBITA and

EBITDA are old and well known financial concepts within the

financial/business arts; and that EBITA is merely EBITDA without

depreciation.); and

(d)   said EBITDA comprising earnings before interest, taxes, depreciation and

amortization (Perley: pg. 4, par. [0050]) (Examiner notes that EBITA and

EBITDA are old and well known financial concepts within the

financial/business arts.).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Perley with the combined teachings of Ash, Filippo, Fletcher-

Haynes, Seare, Siegrist and Deutsch with the motivation of providing a method of

managing information relating to a financial capacity of a business/organization (Perley:

pg. 2, par. [0012]).

(B)   Claims 12 and 15 substantially repeat the same limitations of Claim 6, and are

therefore rejected for the same reasons given for that claim.

8.   Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash,

Filippo, Fletcher-Haynes, Seare, Siegrist and Deutsch as applied to claims 1-5 and 7-9

above, and further in view of Brierton (6,234,989; hereinafter Brierton), further in view of

Tanaka et al. (6,022,512; hereinafter Tanaka) and further in view of Brugger

(5,685,835).

(A)   As per Claim 10, Ash discloses a process as in Claim 1 wherein said treatment

comprises:

(a)   preparing a dialysis fluid for the patient (Ash: col. 1, lines 37-49; col. 9,

lines 36-67 and col. 10, lines 1-2; Figs. 1-3B);

(b)   a dialysis machine with a dialyzer cartridge having a filter (Ash: col. 10,

lines 39-67 and col. 11, 1-46);

(c)   passing the removed blood through a semipermeable membrane (Ash:

col. 10, lines 39-67 and col. 11, 1-46);

(d)   circulating the dialyzer fluid from said monitor through said semipermeable

membrane (Ash: col. 10, lines 39-67 and col. 11, 1-46); and

(e)   returning the treated blood which has passed through said semipermeable

membrane to said patient via said needle or catheter and said tubing (Ash:

col. 10, lines 39-67 and col. 11, 1-46).

Ash, however, fails to expressly disclose a process as in Claim 1 wherein said

treatment comprises:

(f)   preparing the patient for said treatment;

(g)   injecting an injector into said patient, said injector consisting of a needle;

(h)   removing blood from the patient through the needle or catheter via tubing

        connected to a monitor;

 (i)   monitoring the treatment with said monitor;

 (j)   cleaning the monitor after treatment by disinfecting, sterilizing or sanitizing

        the monitor with heat or a chemical disinfectant;

(k)   discarding the tubing after treatment; and

 (l)   processing the cartridge after treatment by a method selected from the

        group consisting of discarding the cartridge after treatment and cleaning

        the cartridge after treatment for reuse.

Nevertheless, these features are old and well known in the art, as evidenced by

Brierton, Tanaka and Brugger. In particular, these prior art references disclose a

process as in Claim 1 wherein said treatment comprises:

(e)   preparing the patient for said treatment (Brierton: col. 52, lines 1-15);

(f)   injecting an injector into said patient, said injector consisting of a needle

        (Brierton: col. 49, lines 1-14) (Examiner has noted insofar as Claim 10

        recites "selected from the group consisting of a needle and a catheter," a

        needle has been recited);

(g)   removing blood from the patient through the needle or catheter via tubing

        connected to a monitor (Brierton: col. 49, lines 1-14);

(h)   monitoring the treatment with said monitor (Brierton: col. 11, lines 10-35);

(i)   cleaning the monitor after treatment by disinfecting, sterilizing or sanitizing

the monitor with heat or a chemical disinfectant (Tanaka: col. 2, lines 52-

57; col. 6, lines 36-49);

(j)   discarding the tubing after treatment (Brugger: col. 11, lines 53-67 and col.

12, lines 1-25); and

(k)   processing the cartridge after treatment by a method selected from the

group consisting of discarding the cartridge after treatment and cleaning

the cartridge after treatment for reuse (Tanaka: col. 6, lines 36-49).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Brierton with the combined teachings of Ash, Filippo, Fletcher-

Haynes, Seare, Siegrist and Deutsch with the motivation of facilitating and enhancing

the extracorporeal blood processing (Brierton: abstract; col. 10, lines 7-19).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Tanaka with the combined teachings of Ash, Filippo, Fletcher-

Haynes, Seare, Siegrist, Deutsch and Brierton with the motivation of providing a

cleaning and disinfecting method for dialysis equipment (Tanaka: col. 3, lines 37-40).

One of ordinary skill would have found it obvious at the time of the invention to

combine the teachings of Brugger with the combined teachings of Ash, Filippo, Fletcher-

Haynes, Seare, Siegrist, Deutsch, Brierton and Tanaka with the motivation of providing

a method of disinfecting a contaminated disposable tubing set used in a dialysis

procedure (Brugger: col. 3, lines 50-53).

(B)   Claim 20 substantially repeats the same limitations of Claim 10, and is therefore

rejected for the same reasons given for that claim.

Conclusion

9.   The prior art made of record and not relied upon is considered pertinent to

Applicant's disclosure. The cited but not applied art teaches a device and method for

preparing a treatment liquid by filtration (6,039,877); an apparatus for extracorporeal

treatment of blood (3,946,731); activity based cost tracking systems (5,732,401); a

medical facility and business system having automatic interactive dynamic real-time

management (5,748,907); a dialyzer clearance check system (5,110,477); a heat

disinfection of a water supply (6,251,279); a technique for automatically preparing a

dialysis machine at a predetermined date and time (H1658); an artificial kidney for

frequent (daily) hemodialysis (5,336,165); a portable machine for regenerative dialysis

(4180460); a dialysis machine with a device for preparing dialysis solutions (US

2001/0040127); methods and systems for asset management (US 2001/0056357); and

a dialysis machine and a method of operating a dialysis machine (6,595,944).

The cited but not applied prior art also includes a non-patent literature textbook by Peter S. Pande, Robert P. Neuman, and Roland R. Cavanagh ("The Six Sigma Way" 2000. McGraw-Hill. pgs. x-xi.).

10.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.
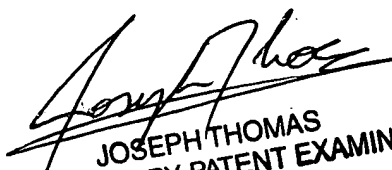
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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